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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/692,257
Filing Date: October 19, 2000
Appellant(s): MILLER ET AL.

Thomas E. Holsten
David R. Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 24, 2005.

A statement identifying the real party in interest is contained in the brief.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

In particular, Appellants brief identifies the related decision by the Board in *In re Fisher* (U.S. Application No. 09/619,643, B.P.A. I. Appeal No. 2002-2046, Fed. Cir. Case No. 04-1465).

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1 and 8-13 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

6068974	***Klann***	***5-2000***

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claim Rejections - 35 USC § 101

Claims 1 and 8-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

The claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any polynucleotide. The specification discloses many potential uses for the polynucleotide including identifying promoters involved in gene regulation (pg. 37, lines 13-27 to pg. 38, lines 1-6), determining whether a plant contains a mutation (pg. 14, lines 10-27 to pg. 15, lines 1-12 and pg. 38, lines 7-27), and acting as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (pg. 46, lines 4-46). These are non-specific uses that are applicable to polynucleotides in general and not particular or specific to the polynucleotide claimed. Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility

has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the promoters, mutations, or genes that are to be identified as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, mutations, and genes does not constitute a specific and substantial utility. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the polynucleotides such that another non-asserted utility would be well established for the compounds.

B. Claim Rejections - 35 USC § 112, first paragraph (Enablement)

Claims 1 and 8-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a "specific or substantial" asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in re Wands, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex

parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to a substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO:1 or its complement. The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims broadly any variants and fragment of SEQ ID NO: 1 DNA, predicting protein structure from sequence data

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely difficult. It would require significant study to identify the actual function of the maize protein, and identifying a use for this protein would be an inventive, unpredictable and difficult undertaking in itself. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. the sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites, and determinants of antigenicity. These regions can tolerate only relatively conservative substitute or no substitute (See Wells, Biochemistry, 1990, 29, pg. 8509-8517; Ngo et al. The Protein Folding Problem and Tertiary Structure Prediction, pg. 492-495).

This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The unpredictability of the art and the state of the prior art

The art is extremely unpredictable with regard to protein function in the absence of reliable information regarding the protein function.

Working Examples

The specification has working example in which cDNA libraries are constructed but the working example lacks sufficient information regarding how the nucleic acid molecule that encodes a maize protein or fragment comprising a nucleic acid sequence of SEQ ID NO: 1 or its complement is purified.

Guidance in the Specification.

Applicant has provided little or no guidance beyond the presentation of sequence data to enable one of ordinary skill in the art to determine the positions in the protein, which are tolerant to change (e.g. amino acid substitutions or deletions). Thus, the specification did not teach any actual function of the nucleic acid sequence of SEQ ID NO: 1 and its complement.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

Although the specification outlines art-recognized procedures for producing and screening for active muteins, this is not an adequate guidance as to the nature of active derivatives that may be constructed, but is an invitation to the artisan to use the current invention

as a starting point for further experimentation. The art recognizes that function cannot be predicted from structure alone (Bork, Genome Research 2000, 10, pg. 398-400; Skolnick et al. Trends in Biotech, 2000, 18(1), pg. 34-39, especially p. 36 at Box 2; Doerks et al. Trends in Genetics, 1998, 14: pg. 248-250; Smith et al, Nature Biotechnology, 1997, 15: pg. 1222-1223; Brenner, Trends in Genetics, 1999, 15: pg. 132-133; Bork, Trends in Genetics, 1996, 12: pg. 425-427). Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims, the claims fail to recite any structural or functional limitations, undue experimentation would be required by the skilled artisan to make and/or use the claimed invention in its full scope.

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the presence of a working example which does not address the issue of the utility of the claimed nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1 or its complement. It is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

C. Claim Rejections - 35 USC § 112, first paragraph (Written Description)

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to a maize protein. The breadth of enablement is not commensurate in scope with the claims. The specification discloses very narrow working examples as compared to the wide breath of the claims at issue. Furthermore, EST technology is highly unpredictable. Thus, the teachings set forth in the specification provides no more than a "plan" or "invitation' for those skilled in the art to experiment using the technology in other type of cells.

D. Claim rejections-35 USC 102

The rejection was withdrawn as set forth in the advisory office action mailed May 27, 2005. The rejection is moot.

(11) Response to Argument

A. Claim Rejections - 35 USC § 101 (Utility)

The appeal brief filed May 24, 2005 traverses this rejection. Appellant's arguments have been fully considered but are not persuasive for the reasons that follow.

At pages 6-7 the brief traverses that the lack of utility analysis misstates the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" and applies case law in support for the doctrine of "practical utility" and the requirement for "identifiable benefit". These arguments are not specifically drawn to the rejection set forth previously or above, and are an allegation. They are found non-persuasive and are reasonably an introductory summary set forth by the brief. As a preliminary matter, the rejections in this application are made in order to comply with office policy regarding the utility guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.). So to the extent that any argument conflicts with the guidelines, it will necessarily be non-persuasive.

Appellants assert at page 5 and pages 8-9 that they have met the conditions of providing the public with an invention having substantial utility wherein specific benefit exists in currently available form. Appellants state that, in particular, the claimed nucleic acids can be used to identify the presence or absence of a polymorphism. However, this is not considered to be a specific and substantial utility. The utility is not specific because it is a property of all nucleic acids that they could be used to search for and try to identify a polymorphism. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. All discussions regarding polymorphisms in the specification are generic in nature. The specification does not teach any particular polymorphisms in SEQ ID NO: 1. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 1 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of maize plant. Therefore, the nucleic acids of SEQ ID NO: 1 may only be used to search for polymorphisms and if such polymorphisms are identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

As set forth in the MPEP (2107):

On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
(B) A method of treating an unspecified disease or condition;
(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
(D) A method of making a material that itself has no specific, substantial, and credible utility; and
(E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

Each of these situations closely matches Appellant's disclosed uses. These uses do not define substantial utilities.

Further, MPEP 2107 states that:

> An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring.

However, in the present situation, the specification does not disclose a correlation between such polymorphisms and any conditions or traits.

Appellants assert that the use of the claimed nucleic acids to detect a polymorphism is analogous to the utilities associated with a microscope, i.e., the claimed nucleic acids may be used to locate and measure nucleic acid molecules in a sample, cell or organism. However, the use of a nucleic acid to detect a polymorphism is not considered to be analogous to the use of a microscope. The microscope can be used to immediately provide information. For instance, the microscope can be used to identify or distinguish between gram-positive and gram-negative bacteria. This use is well known and its benefits are immediately recognizable. The use of a nucleic acid to detect a polymorphism does not provide information of immediate benefit. If a researcher determines that a polymorphism is present, the researcher would not know what to do

with this information since the specification has not disclosed a specific association between any particular polymorphisms and any particular traits. This situation is significantly distinct from a situation in which a nucleic acid is to be used to detect a previously disclosed polymorphism known to be associated with a specific trait. In such a situation, the nucleic acid would have a specific and substantial utility because the information obtained by detecting the polymorphism is specific and of immediate benefit. In contrast, the present invention requires the researcher to first identify a new polymorphism and then determine whether this polymorphism is associated with any particular trait or condition. The information gained by detecting an unknown and uncharacterized polymorphism is not specific and not of immediate benefit.

Appellants assert that the use of the claimed nucleic acid molecules to detect the presence or absence of a polymorphism is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas. However, the gas chromatograph example set forth by Appellant is not analogous to the present disclosure. A gas chromatograph is a piece of equipment designed and built for a particular use. Such equipment is fully tested, evaluated and calibrated to ensure accurate results. Those skilled in the art know how to use the gas chromatograph to analyze both known and unknown samples. When a sample is unknown, the results may be compared to a standard or reference. However, Appellants have not tested, evaluated or calibrated the claimed nucleic acids for any particular use. Screening for the presence or absence of chlorine in a sample is not equivalent to screening for the presence or absence of an unknown polymorphism. Given that the composition and features of chlorine are well known in the art, the detection of chlorine in a sample has a known meaning to those in the art based upon prior research. In the example discussed in the brief, absent an association

between the presence of chlorine and the destruction of a catalyst, the presence or absence of chlorine in a sample would not provide any useful information to the refinery manager. Likewise, the presence or absence of any of the claimed nucleic acids in a sample (or a polymorphism) has no meaning absent an association between the nucleic acid or polymorphism and some other property. Further experimentation is required to determine what that meaning or association might be.

Appellants assert that the specification teaches that the nucleic acids may also be used as markers and probes; to identify and obtain nucleic acid homologues, in microarrays as gene-specific targets; for transformation of plants; to determine the level or expression of a protein or mRNA; to overexpress or suppress a desired protein. However, these utilities are all generic and are characteristic of all nucleic acids. Such uses do not constitute a specific utility. As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined. The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 1 or a protein encoded by SEQ ID NO: 1 or an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods, which determine the expression of an mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids. Additionally, the use of the claimed nucleic acids as a probe to detect itself does not constitute a specific utility because the result of such a use would be meaningless without additional information regarding the significance of the nucleic acid. The use of the claimed nucleic acids to detect homologues in

other plants and organisms such as alfalfa and barley, as argued at page 9 of the brief, is also not a substantial and specific utility. Since the functional activity of the presently claimed nucleic acids is unknown, and the functional activity of any putative homologues is unknown, the detection of such homologues does not provide an immediate benefit and serves only as a starting point for further research. In addition, the use of a nucleic acid in a microarray does not confer a patentable utility since all nucleic acids may be used in microarrays. Each of these asserted utilities are generic, rather than specific. Use of the claimed nucleic acids in the above manners would not be meaningful in the absence of information regarding the specific biological activity or significance of these nucleic acids.

Appellants assert that the claimed nucleic acids may be used to initiate a chromosome walk to identify, e.g., a promoter in the corresponding gene. However, the specification fails to demonstrate that the claimed nucleic acids could in fact be used to obtain any meaningful results from such a search. The specification does not define the structural or functional properties of any promoters associated with SEQ ID NO: 1. Even if such a promoter exists, there is no specific guidance provided in the specification for identifying the promoter. For instance, the specification does not disclose the location of the promoter, the distance between the promoter and the claimed nucleic acids, or the sequence of the promoter. Initiation of a chromosome walk at the corresponding chromosomal location is considered a non-specific utility because any EST would serve this purpose for isolating an uncharacterized promoter since any chromosomal location would be linked to some promoter. Additionally, since the specification does not describe the corresponding promoter, or any other specific nucleic acid molecule, sufficient to inform one in the art that it has been isolated, there can be no "immediate benefit to the public"

in using the claimed nucleic acid molecules in this manner. Appellants assert that the claimed nucleic acid molecules are particularly useful to identify markers and isolate promoters functional in anthers in *Triticum aestivum*, however any nucleic acid similarly isolated as the claimed nucleic acid might be used as such. The specification teaches no function or activity for the protein that SEQ ID NO: 1 might encode, nor teaches which "important genes" associated with plant growth, quality, and yield would be isolated by the claimed SEQ ID NO: 1, or what "important developmental, metabolic, and catabolic pathways" SEQ ID NO:1 may be a link to. Plant nucleic acids, in general, could be used to "isolate agronomically important genes associated with plant growth, quality, and yield" and could serve as "links in important developmental, metabolic and catabolic pathways." However, the specification provides no specific, or substantial utility that takes advantage of the particular combination of nucleotides in the presently claimed nucleic acid molecule.

At page 11 of the brief, Appellants draw an analogy between golf clubs and nucleic acids. It is stated, "a new golf club has no legal utility because other golf clubs can be used for the same purpose, i.e., hitting golf balls." Appellants cite *Carl Zeiss Stiftung v. Renishaw PLC* in support of their arguments. However, the cited decision was made with respect to a mechanical device and not with respect to a molecular compound to be used as a laboratory reagent or a research tool. The facts of the cited case do not correspond to those of the instant application since the utilities associated with a golf club do not compare to the utilities associated with a nucleic acid. While one knows how to use a golf club in a specific manner, one does not know how to use the claimed nucleic acids in a specific manner. The specification does not teach the skilled artisan how to use the claimed nucleic acids for a specific purpose (such as to "hit the ball in a manner

that is distinct from other clubs"). Rather, the specification invites the skilled artisan to perform experimentation in order to determine how to use the claimed nucleic acids for a specific purpose.

At page 13, the brief traverses the rejection by arguing that there is no question that the public has recognized the benefits provided by the claimed subject matter. It is asserted that a multi-million dollar industry has been established with ESTs. However, the evidence provided by Appellants shows that a multimillion dollar industry has arisen surrounding buying and selling EST databases and clones. Appellants have not established the market value of the presently claimed ESTs. Further, it is noted that simply because a product, such as an EST sequence database or a clone library, is bought and sold does not mean that the product has patentable utility.

With regard to Appellant's arguments concerning credibility, the credibility of the asserted uses has not been challenged. It is acknowledged that detection of a polymorphism, for example, constitutes a credible utility. Appellant is reminded that in order to meet the requirements of 35 U.S.C. 101, the specification must disclose at least one utility that is specific and substantial, as well as credible (absent a showing of a well established utility, which would presume that the utility was credible). In the instant situation, the claims remain rejected because the specification does not disclose at least one use that is specific and substantial and no convincing evidence has been provided to show that the disclosed EST, for which only a nucleotide sequence and source have been provided, has a well established utility. Accordingly, the lack of utility remains because there is no well established utility or a specific and substantial utility for the claimed invention.

As set forth above, the rejection is based on the finding that Appellants have not disclosed a substantial and specific or well-established utility for the claimed invention. The facts supporting this conclusion are clearly set forth throughout the rejection. The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966) wherein the court held that 35 U.S.C. 101 requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion."

In the present situation, Appellants have not arrived at a "successful conclusion" as to the actual functional role or significance of the claimed nucleic acids. Without such information, the claimed nucleic acids can only be used as a starting point for conducting further experiments to arrive at a "successful conclusion."

B. Claim Rejections - 35 USC § 112, first paragraph (Enablement)

The brief at page 15 states that this rejection is erroneous and has been overcome by the arguments stated above regarding utility. However, for the reasons set forth above, it is maintained that the uses asserted for the claimed invention are an object of study and are not specific, nor substantial. The specification cannot enable or teach one how to use the invention within 35 U.S.C. 112, first paragraph, if there is no patentable utility within 35 U.S.C. 101. Because there is no utility for the claimed invention for the reasons set forth above, it is maintained that the specification has not enabled the claimed invention.

C. Claim Rejections - 35 USC § 112, first paragraph (Written Description)

The brief traverses the written description rejection. It is argued that the specification demonstrates that Appellant was in possession of the claimed genus of nucleic acid molecules. It is further asserted that the fact that the claims are joined with additional sequences, or complements of the recited sequence or nucleic aid molecules that share a claimed identity with the recited sequence does not mean that Appellant was any less in possession of the claimed nucleic acid molecules. This argument was thoroughly reviewed but was not found persuasive. The rejection is based on the fact that the claims include full length genomic sequences comprising the recited SEQ ID NO: 1. With regard to claim 8, the specification provides no description as to attributes, which would make a sequence as claimed in claim 1, encode a maize protein, as opposed to any protein in general. Thereby, the claims encompass mutants, allelic variants, splice variants and homologues of SEQ ID NO: 1, which are not adequately described in the present specification.

Appellants state that the application describes more than just the nucleotide sequence of SEQ ID NO: 1. It is asserted that the specification describes vectors comprising the claimed nucleic acid molecules, the addition of other nucleotides or detectable labels, fusion peptides, as well as sequences having particular sequence identity to claimed nucleic acid molecules. Appellants cite Enzo Biochem (Fed. Cir. 2002) as stating that the written inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, mixtures of those sequences are also described to one of skill in the art."

These arguments have been fully considered but are not persuasive. The genus of nucleic acids encompassed by the claims is extremely broad and is not limited to vectors comprising the nucleic acids or to nucleic acids comprising a label. The claims further encompass mutants, allelic variants, splice variants and homologues of SEQ ID NO: 1. A general statement in the specification of a desire to obtain gene sequences, homologues from other species, mutated species, SNPs, polymorphic sequences, promoter sequences and exogenous sequences is not equivalent to providing a clear and complete description of specific sequences which fall within the claimed genus of nucleic acids. As discussed in the rejection, the court in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), held that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". While Appellants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. In the present situation, Appellants have provided only a disclosure of a wish to obtain homologues, mutant, allelic, and splice variants of SEQ ID NO: 1. The specification does not disclose any specific mutant, allelic, or splice variants or homologues of SEQ ID NO: 1. Further, the functional activity of such variants is not disclosed. Accordingly, the specification has not disclosed a representative number of nucleic acid molecules within the claimed genus.

Appellants assert that they have disclosed the common structural features of the claimed nucleic acids, i.e., SEQ ID NO: 1. However, the claims are not limited to nucleic acids, which share this common structural feature. Rather, the claims encompass fragment thereof comprising

a nucleic acid sequence of SEQ ID NO: 1 or its complement. Thereby, the claimed genus of nucleic acids do not share the same common structural feature of containing the sequence of SEQ ID NO: 1. Appellants have not disclosed what specific sequence information must be shared by the claimed genus of nucleic acid molecules in order to ascertain which nucleic acids share a common structural feature. The genus of molecules having fragment thereof comprising a nucleic acid sequence of identity with SEQ ID NO: 1 includes individual species of nucleic acids which may vary from SEQ ID NO: 1 at any given nucleotide position within SEQ ID NO: 1. When the individual species within the genus are compared to one another, together this genus comprises nucleic acids which vary at each and every nucleotide position within SEQ ID NO: 1. Accordingly, the genus of nucleic acids are not considered to share a common structural feature – i.e., there is no specific structural property that is common to all members of the claimed genus if each of the individual nucleotides may be varied. Further, the claims do not recite a functional requirement for any of the claimed nucleic acids and thereby encompass nucleic acids having distinct functional properties.

At page 21, Appellants state that "closely related nucleic acid molecules falling within the scope of the invention are readily identifiable – they either contain the nucleic acid sequence of SEQ ID NO: 1 or share a claimed identity with SEQ ID NO: 1, or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. Thus, contrary to the Examiner's analysis, claim 1 is supported by an adequate written description." These arguments have been fully considered but are not found persuasive. It is noted that the criteria for meeting the Written Description requirement is not

limited to providing a means for distinguishing between molecules which fall within the claimed genus and molecules which fall outside the claimed genus. Rather, the Written Description requirement is met by providing a showing that Appellants were, at the time the application was filed, in possession of the claimed invention. Providing a statement that the invention covers nucleic acid having fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1 or its complement is not equivalent to disclosing specific nucleic acids which fall within the claimed genus of nucleic acids. The specification does not disclose a single molecule within the genus of nucleic acids having fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1 or its complement. The specification does not describe the location or identity of nucleotides which may be varied within SEQ ID NO: 1, and does not describe the functional activity or other biological role associated with such variants. The specification also does not disclose any specific variants of SEQ ID NO: 1 which have a functional activity or biological role distinct from that of SEQ ID NO: 1. Modification of a nucleic acid sequence by 1 to 5% can significantly alter the functional activity of the nucleic acid and the protein encoded thereby. The genus of nucleic acids claimed is large and variable, and potentially includes nucleic acids encoding for proteins having diverse biological functions. The specification discloses only one member of this genus, i.e., SEQ ID NO: 1. This is not sufficient to place one of skill in the art in possession of a representative number of molecules having the varied attributes and features of species within the claimed genus. Accordingly, it is maintained that the written description requirements have not been adequately met for the broadly claimed genus of homologues, splice, mutant and polymorphic variants of SEQ ID NO: 1.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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August 31, 2005

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